

### **REMARKS**

Undersigned counsel thank Examiners Ton and Voitach for extending the courtesy of a personal interview on November 18, 2004 to discuss the outstanding Office Action and the contents of this Response.

#### **Status of the Claims**

Upon entry of this paper, claims 1, 14, and 27-55 will be pending in this application. Solely in the interest of timely prosecution, and without acquiescing to the propriety of the rejections, claims 2-13 and 15-26 have been cancelled. Applicants retain, however, the right to pursue the cancelled subject matter in a continuation application.

Applicants respectfully request entry of the amendments and remarks made herein into the prosecution history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

#### **Support for Amendments/ New Claims**

Claims 1 and 14 have been amended; claims 27-55 are new. Support for the amendments may be found throughout the specification, the as-filed claims and Section 6.1 of the specification. Support for “a composition comprising a population of isolated single cells *enriched in* bipotent hepatic progenitors...” may be found at, at least, page 13, lines 13-18 of the specification and in the abstract. Accordingly, Applicants submit that no new matter has been

added by this amendment and no new search on behalf of the Examiner is required.

Reconsideration and allowance of all the claims is respectfully requested.

### **Elections/Restrictions**

Examiner has withdrawn claims 21-24 from further consideration for being drawn to a non-elected group, there being no allowable generic or linking claim. Applicants have cancelled claims 12-18 with this amendment.

### **Claim Rejections under 35 U.S.C. § 112, second paragraph**

Claims 1-20 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the Applicants regards as the invention. More specifically, during the interview the Examiners noted that the words “composition comprising isolated single-cell bipotent hepatic progenitors” are unclear in that, for example, the claimed subject matter could encompass single bipotent hepatic progenitor cells present in a whole liver. Applicants maintain that it is not their intent to claim a whole liver.

Without acquiescing in the propriety of the rejection, claims 1 and 14 have been amended to clarify what was implied in the original claim language. One of ordinary skill in the art would appreciate from the disclosure that Applicants’ single-cell suspensions are not to be equated with whole liver or minced portions thereof. Applicants respectfully note the specification adequately describes what is meant by single-cell suspensions. The specification recites at page 14, lines 8-10 that single cell suspensions are obtained, for example, by incubating the livers with 0.05% trypsin and 0.5mM EDTA or 10 units/ml thermolysin (Sigma, St. Louis, MO) and 100 units/ml

deoxyribonuclease I (Sigma) for at 37 °C. One of ordinary skill in the art is able to obtain single-cell suspensions by other analogous methods.

Thus, Applicants submit respectfully that the claims, as amended, are not unclear. Applicants request respectfully that the 35 U.S.C. § 112, second paragraph, rejection of the pending claims be withdrawn.

### **Claim Rejections under 35 U.S.C. § 102**

The Office Action, at pages 2-5, rejects claims 1-20 as allegedly being anticipated by Sargiacomo *et al.* (*J. Hepat.*, 28:480-490, 1998) (hereinafter, “Sargiacomo”), as further evidenced by Haruna *et al.* (*Hepatology*, 23:476-481, 1996) (hereinafter, “Haruna”), under 35 U.S.C. § 102(b). In particular, the Office Action states that the breadth of the claims read on, for example, an isolated fetal liver, or minced-up fetal liver, as taught by Sargiacomo. “It is maintained that Sargiacomo’s teaching of cultures of human fetal liver cells, with the evidence provided by Haruna, who identify bipotent progenitor cells in fetal human livers,... would inherently contain bipotent hepatic progenitor cells.” Applicants traverse respectfully.

Applicants submit respectfully that amended claims 1 and 14 as well as the newly added claims are not anticipated by the prior art. Fundamental to Sargiacomo’s method is the use of *intact* “multi-size spherical hepatic units” so that hepatic architecture would be present. In fact, Sargiacomo teaches that the use of intact, 3-dimensional cell clusters is a cure to deficiencies noted in the art. (See sentence bridging pages 480-481.) The claimed invention, however, is directed to *isolated, single cell* hepatic progenitors (claims 1, 14); compositions *consisting essentially of* isolated single cell hepatic progenitors (claims 27 and 28); or compositions comprising a population of isolated single cells *enriched in* bipotent hepatic progenitors.

Applicants maintain that Sargiacomo, even in combination with Haruna, does not teach or disclose single cell populations enriched for and/or consisting essentially of the inventive hepatic progenitor cells. Accordingly, Applicants submit respectfully that the claims of the present invention, as pending, are not anticipated by the prior art, which do not teach or suggest each and every element of the present claims, and that the rejection under 35 U.S.C. § 102(b) has been overcome. Applicant requests respectfully that the rejection under 35 U.S.C. § 102(b) be withdrawn.

**CONCLUSION**

Applicants submit that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,



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